

## REMARKS

An Office Action was mailed on January 28, 2004. Claims 1-9 are pending.

Claims 1-3, 5-6 and 9 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ochiai et al. (U.S. Patent 4,018,230), while claims 4 and 7-8 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ochiai et al. in view of Hammersen (EP 0 663 197). The Examiner notes that Figure 11 of Ochiai et al. shows a balloon of various sizes and that it would have been obvious to construct a balloon with the sizes as claimed.

Applicant respectfully disagrees with the Examiner that the Ochiai et al. reference either alone or in combination with Hammersen teaches or suggests the claimed invention. Ochiai et al. describes a cervical dilator comprising a flat head with a cylindrical stem. The dilator is inserted with the head portion folded through the cervix opening and expanded afterwards. However, its expansion is limited by a network of interconnected, inelastic members. As shown in Figure 11 of Ochiai et al., the dilator is expanded slowly in order to dilate the cervix with rising hydraulic pressure from the pump.

In contrast with the claimed invention, Ochiai does not teach using a substantially conically shaped application region, which is a requirement of the present claims. The Examiner is respectfully directed to column 3, lines 53 to 58 of Ochiai et al.:

*...Further more, this device is designed so that it may be expanded slowly by pressure and amount of water as shown in FIG 11, and condition of device within the cervix may be conceived by the amount of pouring water, and in addition the dilating rate of cervix may also be controlled in accordance with the condition.*

Applicant respectfully submits that the Examiner's interpretation of Ochiai et al. and the Examiner's argument that Ochiai et al. could be inflated to the same cone angle is manifestly inappropriate, because the goal of the Ochiai et al. device is not to produce anything having a "cone angle." Nor is there any disclosure in Ochiai et al. to provide for a substantially conically shaped application region.

As the CAFC stresses for a § 103 rejection to stand, the Examiner is required to show with evidence the motivation, suggestion or teaching of the desirability of arriving at the claimed invention from the cited art. That evidence is required to counter the powerful attraction of a hindsight-based obviousness analysis. See, for example, *In re Lee*, 277 F.3d 1338, 1343, 61

U.S P.Q. 2d 1430, 1433 (Fed. Cir. 2002) ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references"). It is respectfully submitted that this involves more than a mere bald assertion that it would be obvious to arrive at the claimed invention because the structure of the prior art could possibly be manipulated to arrive at the structure as particularly claimed. With respect to the §103(a) rejection in view of Ochiai et al. alone, the Examiner has failed to indicate why one of ordinary skill in the art would be taught or motivated to transform the balloon of Ochiai et al. to the balloon as claimed in the present application. The claims of the present application clearly require that the application region (P) of the balloon adjoins the outer end of the crown region of the balloon in a conical portion, where it extends between an outer portion (a) and an inner portion (i) of the balloon approximately within the middle third of the balloon length, and in that the cone angle ( $\beta$ ) in the application region is  $25^\circ$  or smaller. *In re Lee* requires that the record must state with particularity all the evidence and rationale on which the PTO relies for a rejection and sets out that it is necessary to explain the reasons one of ordinary skill in the art would have been motivated to select the Ochiai et al. reference to render the claimed invention obvious.

Under *Lee*, the PTO must state in writing **the evidence** on which it bases its rejection. With respect, the present office action falls woefully short of this requirement, and it is clear that the only way one skilled in the art could possibly arrive at the claimed invention from the teaching of Ochiai is through the application of improper hindsight.

Accordingly, the Examiner is respectfully requested to withdraw the §103(a) rejections to claims 1-3, 5-6 and 9 in view of Ochiai et al., and to claims 4 and 7-8 in view of Ochiai et al. and Hammersen through dependency. Applicant is also presenting herewith new claim 10 for consideration of the Examiner, which is similar in content to pending claim 3 but slightly broader in scope.

With respect to Hammersen, the Examiner is directed to column 2, lines 11 to 14, wherein a balloon-like body is described reducing its shape in direction of its fitting, "whereby its shape in this area (between its crown region and said fitting) is of minor importance", or in German "*wobei die Formgebung an dieser Stelle von untergeordneter Bedeutung ist.*" Again,

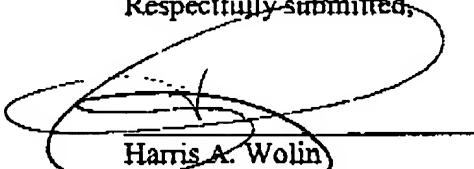
with Hammersen there is no teaching of a specific application region with exception of its opposed walls (3) and (4) which are applied to stabilize the vagina between its outer and inner end after the balloon has been inserted and inflated. Therefore also with Hammersen there is no teaching to use a conical application region. The specific shape of the balloon with Hammersen is based on the idea to create an easily foldable balloon, which, after its expansion creates a wide inner wall (4) to effectively support the inner end of the vagina in cases of descensus, uterus prolapse or incontinence.

For the foregoing reasons, reconsideration is respectfully requested.

An earnest effort has been made to be fully responsive to the Examiner's objections. In view of the above amendments and remarks, it is believed that claims 1-10, consisting of independent claims 1 and 10 and the claims dependent therefrom, are in condition for allowance. Passage of this case to allowance is earnestly solicited. However, if for any reason the Examiner should consider this application not to be in condition for allowance, the Examiner is respectfully requested to telephone the undersigned attorney at the number listed below prior to issuing a further Action.

Any fee due with this paper may be charged on Deposit Account 50-1290.

Respectfully submitted,



Harris A. Wolin  
Reg. No. 39,432

**CUSTOMER NUMBER 026304**  
**PHONE: (212) 940-8708**  
**FAX: (212) 894-5708 (direct)**  
**DOCKET NO.: GRAT 19.511 (100717-00054)**

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